

01-11-07

PTO/SB/21 (09-04)

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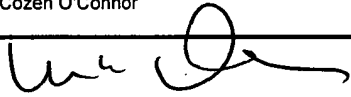
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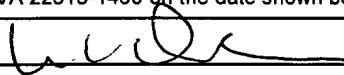
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|--|----------------------|------------------------|----------------------|
| <b>TRANSMITTAL FORM</b><br><small>to be used for all correspondence after initial filing</small> | Application Number   | 10/526,979             |                      |
|  | Filing Date          | May 17, 2006           |                      |
|  | First Named Inventor | Robert Sutherland      |                      |
|  | Art Unit             | To Be Determined       |                      |
|  | Examiner Name        | To Be Determined       |                      |
| Total Number of Pages in This Submission   | 6                    | Attorney Docket Number | FBR0003-100 (122257) |

| ENCLOSURES (check all that apply)  |  |  |
|--|--|--|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment / Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s)<br><small>(please identify below):</small><br>Forms PTO SB/08a and SB/08b (1 p.); 35 References cited; 32 copies of references submitted. |
| <b>Remarks</b> <b>EXPRESS MAIL LABEL NO.: EV 770974175 US</b><br><b>DATE OF DEPOSIT: January 9, 2007</b>   |  |  |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT |   |          |        |
|--|---|----------|--------|
| Firm                                       | Cozen O'Connor  |          |        |
| Signature                                  |  |          |        |
| Printed Name                               | Mark DeLuca.  |          |        |
| Date                                       | 1/9/07  | Reg. No. | 33,229 |

| CERTIFICATE OF EXPRESS MAILING  |   |      |        |
|---|---|------|--------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as EXPRESS MAIL NO. EL 963420785 US in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. |   |      |        |
| Signature   |  |      |        |
| Typed or printed name   | Mark DeLuca   | Date | 1/9/07 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Robert Sutherland et al.**Serial No.: **10/526,979**Group Art Unit: **To be determined**Filing Date: **May 17, 2006**Examiner: **To be determined**For: **Methods of Diagnosis and Prognosis of Ovarian Cancer****EXPRESS MAIL LABEL NO: EV 770974175 US****DATE OF DEPOSIT: January 9, 2007****Mail Stop Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **before** the mailing date of a first Office Action on the merits after the filing of a Request for Continued Examination under § 1.114.

- ☐ **after** the mailing date of a first Office Action on the merits or after the filing of a Request for Continued Examination under § 1.114, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with the ☐ first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), and the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p).
- ☒ Copies of the cited references (except the U.S. Patent Documents) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of references, and the likelihood that these reference are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) \_\_\_\_\_ for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 C.F.R. § 1.704(d)**

- ☐ The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in §1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b) as no first Office Action on the merits has been received by the Applicants.

Respectfully submitted,



Mark DeLuca  
Registration No. 33,229

Dated: January 9, 2007

COZEN O'CONNOR, P.C.  
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Philadelphia, PA 19103-3508  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

|       |   |    |   |
|-------|---|----|---|
| Sheet | 1 | of | 3 |
|-------|---|----|---|

**Complete if Known**

|                               |                   |
|-------------------------------|-------------------|
| <i>Application Number</i>     | 10/526,979        |
| <i>Filing Date</i>            | May 17, 2006      |
| <i>First Named Inventor</i>   | Robert Sutherland |
| <i>Art Unit</i>               | To Be Determined  |
| <i>Examiner Name</i>          | To Be Determined  |
| <i>Attorney Docket Number</i> | FBR0003-100       |

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|---|--------------------------------|---|---|----------------|
|                    |                       | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |   |   |                |
|                    | AD                    | WO 02/071928  | 09-19-2002                     | Millenium Pharm                                 |   |                |
|                    | AE                    | WO 02/102235  | 12-27-2002                     | Eos Bioltech.                                   |   |                |
|                    | AF                    | WO 03/068054  | 08-21-2003                     | U.S. Government                                 |   |                |
|                    | AG                    | WO 02/30268   | 04-18-2002                     | Eos Biotech. Inc.                               |   |                |
|                    | AH                    | WO 01/90304   | 11-29-2001                     | Human Genome Sciences, Inc.                     |   |                |
|                    | AI                    | WO 01/51513   | 07-19-2001                     | Corixa Corp.                                    |   |                |
|                    | AJ                    | WO 01/92581   | 05-29-201                      | Corixa Corp.                                    |   |                |
|                    | AK                    | WO 01/55313   | 08-02-2001                     | Human Genome Sciences, Inc.                     |   |                |
|                    | AL                    | WO 01/60860   | 08-23-2001                     | Millenium Predictive Medicine                   |   |                |
|                    | AM                    | WO 01/94629   | 12-13-2001                     | Avalon Pharm                                    |   |                |
|                    | AN                    | WO 99/53040   | 12-21-1999                     | Metagen Gesellschaft                            |   |                |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 3

**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/526,979        |
| Filing Date            | May 17, 2006      |
| First Named Inventor   | Robert Sutherland |
| Art Unit               | To Be Determined  |
| Examiner Name          | To Be Determined  |
| Attorney Docket Number | FBR0003-100       |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                      | T <sup>2</sup> |
|---------------------|-----------------------|--|----------------|
|                     | AO                    | Costa et al. "Topoisomerase II alpha: prognostic predictor and cell cycle marker in surface epithelial neoplasms of the ovary and peritoneum," <i>Int. J. Gynecol. Pathol.</i> (2000) 19(3):248-57.  |                |
|                     | AP                    | Gotlieb et al., "Topoisomerase II immunostaining as a prognostic marker for survival in ovarian cancer," <i>Gynecol. Oncol.</i> (2001) 82(1):99-104.   |                |
|                     | AQ                    | Hough et al., "Large-scale serial analysis of gene expression reveals genes differentially expressed in ovarian cancer," <i>Cancer Research</i> (2000) 60:6281-7.  |                |
|                     | AR                    | Koshiyama et al. "Immunohistochemical expression of topoisomerase II alpha (TopII alpha) and multidrug resistance-associated protein (MRP), plus chemosensitivity testing, as chemotherapeutic indices of ovarian endometrial carcinomas," <i>Anticancer Res.</i> (2001) 21:2925-32. |                |
|                     | AS                    | Laval et al. "Isolation and characterization of an epithelial-specific receptor tyrosine kinase from an ovarian cancer cell line," <i>Cell Growth Differ.</i> (1994) 5(11):1173-83.  |                |
|                     | AT                    | Sakamoto et al., "Analysis of gene expression profiles associated with cisplatin resistance in human ovarian cancer cell lines and tissues using cDNA microarray," <i>Hum. Cell</i> (2001) 14(4):305-15 (Medline Abstract 11925933).   |                |
|                     | AU                    | Scheurle et al., "Cancer gene discovery using digital differential display," (2000)(online), (retrieved on 16 October 2003) pp. 1-4.   |                |
|                     | AV                    | Shigemasa et al. "Expression of the protease inhibitor antileukoprotease and the serine protease stratum corneum chymotryptic enzyme (SCCE) is coordinated in ovarian tumors," (2001) <i>Int. J. Gynecol. Cancer</i> 11(6):454-61 (Medline Abstract 11906548).                       |                |
|                     | AW                    | Weitzel et al., "Molecular genetic changes associated with ovarian cancer," <i>Gynecologic Oncology</i> (1994) 55:245-252 and GENE BANK ACC M62397.  |                |
|                     | AX                    | DGENE Abstract Accession No. AVQ54626 & WO 02/00677 A1 (HUMAN GENOME SCIENCES, INC.) 3 January 2002.   |                |
|                     | AY                    | DGENE Abstract Accession No. AAS56533 & WO 01/70796 A2 (CORIXA CORPORATION) 27 September 2001.   |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 3

**Complete if Known**

|                        |                   |
|------------------------|-------------------|
| Application Number     | 10/526,979        |
| Filing Date            | May 17, 2006      |
| First Named Inventor   | Robert Sutherland |
| Art Unit               | To Be Determined  |
| Examiner Name          | To Be Determined  |
| Attorney Docket Number | FBR0003-100       |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|---------------------|-----------------------|---|----------------|
|                     | AZ                    | DGENE Abstract Accession No. ABQ54317 & WO 02/00677 A1 (HUMAN GENOME SCIENCES, INC.) 3 January 2002.  |                |
|                     | BA                    | DGENE Abstract Accession No. ACA03948 & US 2002/0192678 A1 (CHEN H-M) 19 December 2002.   |                |
|                     | BB                    | DGENE Abstract Accession No. ABQ54876 & WO 02/00677 A1 (HUMAN GENOME SCIENCES, INC.) 3 January 2002.  |                |
|                     | BC                    | DGENE Abstract Accession No. AAV64871 & WO 98 48010 A1 (GARVAN INSTITUTE OF MEDICAL RESEARCH) 29 October 1998   |                |
|                     | BD                    | Genbank Accession No. AK075046 3 September 2002. Isogai, T et al <i>Homo sapiens</i> cDNA FLJ90565, clone OVARC1001336.   |                |
|                     | BE                    | DGENE Abstract Accession No. ABQ54583 & WO 02 00677 A1 (HUMAN GENOME SCIENCES, INC.) 3 January 2003.  |                |
|                     | BF                    | DGENE Abstract Accession No. ABL62031 & WO 01 94629 A2 (AVALON PHARMACEUTICALS) 13 December 2001.   |                |
|                     | BG                    | Ashburner et al., "Gene Ontology: tool for the unification of biology <i>The Gene Ontology Consortium</i> ," <i>Nature Genetics</i> . (2000) 25-29.   |                |
|                     | BH                    | Clancy et al., "EDD, The Human Hyperplastic Discs Gene, is Amplified Overexpressed in Cancer," <i>Cancer Research Program, Garvan Institute of Medical Research</i> (1p.)   |                |
|                     | BI                    | Saunders et al., "Embryonic lethality in mice with a targeted disruption of EDD, the homologue of the <i>drosophila melanogaster</i> tumour suppressor gene <i>hyd</i> ," <i>Cancer Research Program, Garvan Institute of Medical Research</i> (1p.)            |                |
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| Examiner Signature |  | Date Considered |  |
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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